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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/679,429	10/07/2003	Ramachandra S. Hosmane	46481	3460

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MANELLI DENISON & SELTER
2000 M STREET NW SUITE 700
WASHINGTON, DC 20036-3307

EXAMINER

KHARE, DEVESH

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 01/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/679,429

Applicant(s)

HOSMANE ET AL.

Examiner

Devesh Khare

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-69 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 24-69 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10/07/2003</u> . | 6) <input type="checkbox"/> Other: ____ |

Art Unit: 1623

Claims 1-23 and 70777 have been cancelled by the Preliminary Amendment dated 10/07/2003.

Claims 24-69 are currently pending.

An action on the merits of claims 24-69 is contained herein below.

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 24-69 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-31 of U.S. Patent No. 6,677,310 ('310).

Although the conflicting claims are not identical, they are not patentably distinct from each other because the '310 patent discloses a method of treating a viral infection and hepatitis B, inhibiting the growth of cancer, inhibiting enzymatic activity of RNA polymerases, inhibiting enzymatic activity of adenosine deaminase and/or guanine deaminase in a patient or vertebrate animal by administering to a patient or vertebrate animal at least one of potentially planar, aromatic, ring-expanded heterocyclic bases,

Art Unit: 1623

nucleosides and nucleotides compounds having the structure I (A, B and C) wherein said method is encompassed by or has substantial overlap with the method of the instant claims. However, the instant method is for a method of treating a viral, bacterial, fungal or parasitic infection, inhibiting the growth of cancer, inhibiting enzymatic activity of RNA polymerases, inhibiting enzymatic activity of adenosine deaminase and/or guanine deaminase in a patient or vertebrate animal by administering to a patient or vertebrate animal at least one of compounds comprising non-planar, non-aromatic, ring-expanded heterocyclic bases, nucleosides and nucleotides compounds having the Formulas II-IV by which the method of the issued claims are accomplished. It is noted that the compounds of Formulas II-IV comprising non-planar, non-aromatic, ring-expanded heterocyclic bases, nucleosides and nucleotides of claims 24,34,39,43,47,57,62 and 66 have the same core structure of formula I (A, B and C) of the '310 patent.

The examiner notes the instant claims and the '310 patent claims do indeed substantially overlap and this obviousness-type double patenting rejection is necessary to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees.

Art Unit: 1623

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 24-69 rejected under 35 U.S.C. 102(e) as being anticipated by Hosmane et al. (U.S. Patent No. 5,843,912).

The applied reference has a common inventor with the instant application.

Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

The applicants' claims are directed toward a method of treating a viral, bacterial, fungal or parasitic infection, inhibiting the growth of cancer, inhibiting enzymatic activity of RNA polymerases, inhibiting enzymatic activity of adenosine deaminase and/or guanine deaminase in a patient or vertebrate animal by administering to a patient or vertebrate animal at least one of compounds comprising non-planar, non-aromatic, ring-

Art Unit: 1623

expanded heterocyclic bases, nucleosides and nucleotides compounds having the Formulas II-IV (claims 24,34,39,43,47,57,62 and 66).


Hosmane et al. reference is encompassed by the applicants' claims wherein non-planar, non-aromatic, ring-expanded heterocyclic bases, nucleosides and nucleotides compounds having the Formulas II, III and IV (col. 4, lines 20-25) can be administered to inhibit enzymes of purine metabolism to treat a viral, bacterial, fungal or parasitic infection, inhibiting the growth of cancer, inhibiting enzymatic activity of RNA polymerases, inhibiting enzymatic activity of adenosine deaminase and/or guanine deaminase in a patient or vertebrate animal (col. 15, lines 25-65 and col. 16, lines 5-35).

Any inquiry concerning this communication or earlier communications from the

Examiner should be directed to Devesh Khare whose telephone number is 571-272-0653. The examiner can normally be reached on Monday to Friday from 8:00 to 4:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, Supervisory Patent Examiner, Art Unit 1623 can be reached at 571-272-0661. The official fax phone numbers for the organization where this application or proceeding is assigned is (703) 308-4556 or 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Devesh Khare, Ph.D.,J.D.
Art Unit 1623
January 6,2004


JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600